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| APPLICATION NO.                                                                                                | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/813,856                                                                                                     | 03/30/2004  | Douglas A. Lappi     | 66785-017           | 5576             |
| 7590                                                                                                           | 12/29/2005  |                      | EXAMINER            |                  |
| Cathryn Campbell<br>McDERMOTT, WILL & EMERY<br>Suite 700<br>4370 La Jolla Village Drive<br>San Diego, CA 92122 |             |                      | BORIN, MICHAEL L    |                  |
|                                                                                                                |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                                                                |             |                      | 1631                |                  |
| DATE MAILED: 12/29/2005                                                                                        |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                           |                  |
|------------------------------|---------------------------|------------------|
| <b>Office Action Summary</b> | Application No.           | Applicant(s)     |
|                              | 10/813,856                | LAPPI ET AL.     |
|                              | Examiner<br>Michael Borin | Art Unit<br>1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-24 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|                                                                                                                         |                                                                             |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.                                               |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                         | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

Claims 1-24 are currently pending.

### Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6,8-15, drawn to a polypeptide conjugate and pharmaceutical compositions thereof, classified in class 530, subclass 330.
- II. Claim 7 , drawn to an antibody/protein conjugate, classified in class 424, subclass 178.1.
- III. Claims 16-21, drawn to first method of use of product of Group I, classified in class 514, subclass 02, in general.
- IV. Claim 22 , drawn to second method of use of product of Group I, classified in class 514, subclass 02, in general.
- V. Claims 23, drawn to third method of use of product of Group I, classified in class 514, subclass 02, in general.
- VI. Claim 24, drawn to fourth method of use of product of Group I, classified in class 514, subclass 02, in general.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-II are patentably distinct from each other because are drawn to independent and/or patentably distinct compounds since each of these compounds possess different structure (e.g.,primary, secondary and tertiary structure)

and/or physico-chemical properties, and/or capable of separate manufacture and/or use. There is no identifiable common structure between these products. Accordingly, the examination of the Groups will require different searches of the US Patents and scientific literature and would require consideration of different patentability issues.

Inventions I and III-VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, methods III-VI are alternate methods of using the product of Group I.

Inventions III-VI are related as independent and/or patentably distinct methods which are not connected in design, operation or effect. These methods have different effects and different modes of operation. The groups require different literature search and a reference teaching one method (e.g., treatment of cancer) will not teach another method (e.g., destroying cells). In addition each Group has separate enablement requirements. The examination of the Groups will require different searches of the US Patents and scientific literature and would require consideration of different patentability issues.

Product of inventions II and methods of inventions III-VI are unrelated as the methods do not utilize the product of Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

**Species Requirement**

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

If any one of the of Groups I, III-VI from above is selected, the following election of species is hereby required for the initial search for examination on merits:

The claims of Group are individually or dependently directed to a plurality of disclosed patentably distinct species of polypeptide conjugates comprising different substance P analogs (see claims 3,4) and different proteins (see claims 8,9). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb  
12/27/2005